# Ethical, Legal and Social Implications of Genetic Technologies

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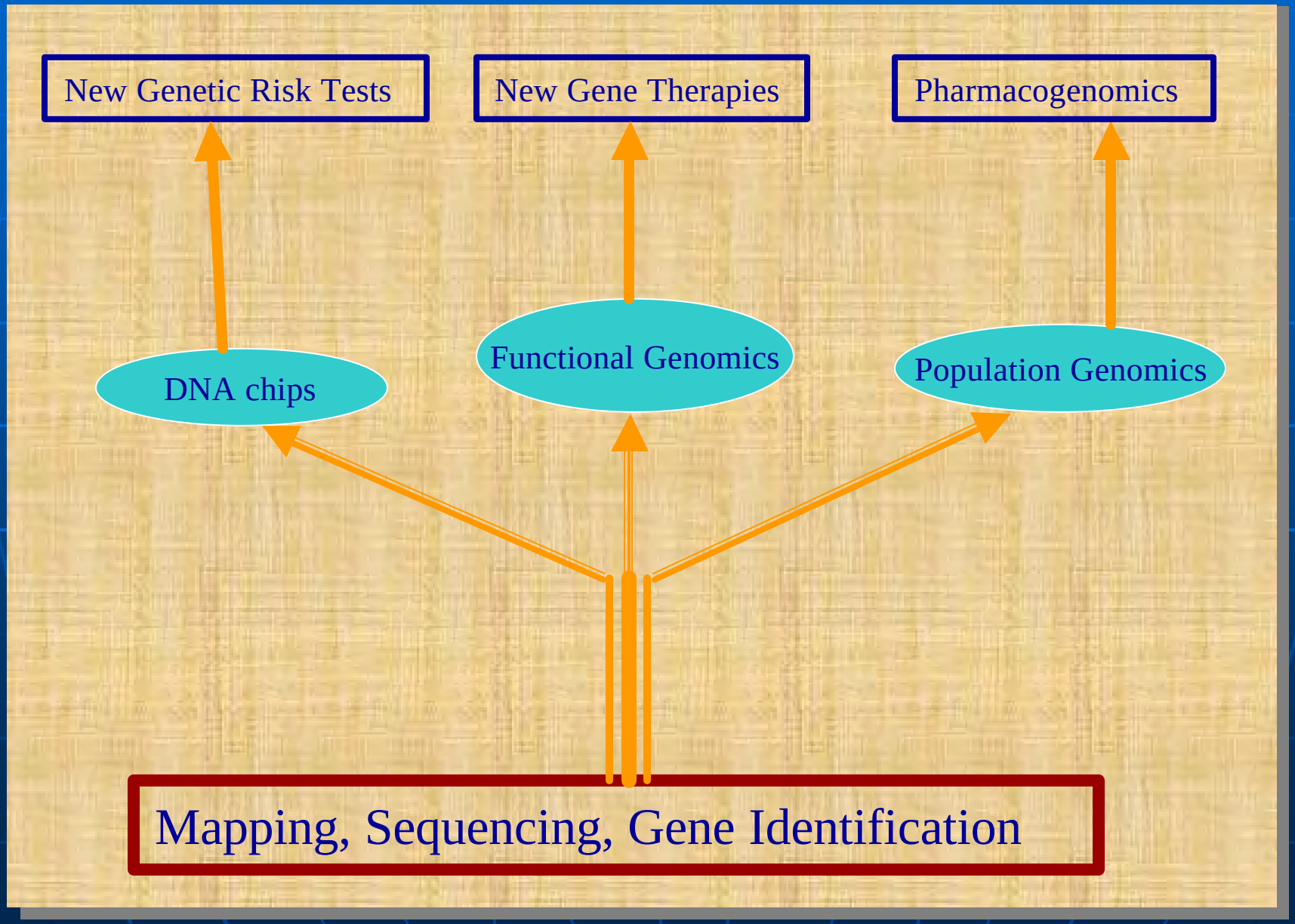
# Post-Genome Project Genomics (after F. Collins)



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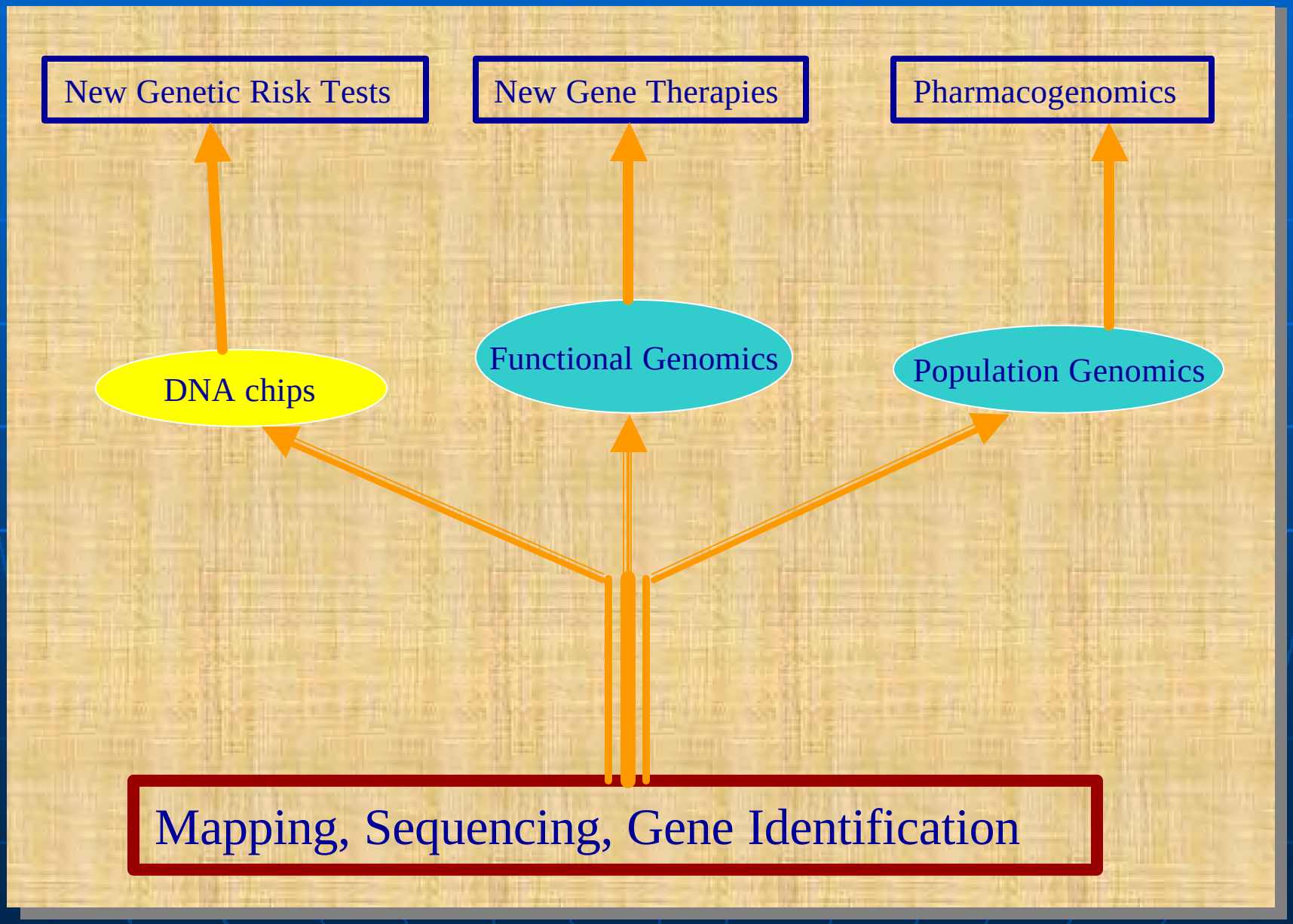

# Fruits of the HGP (after B. Clinton)

- "I think it won't be too many years before parents will be able to go home from the hospital with their newborn babies with a genetic map in their hands that will tell them, here's what your child's future will be like."

- Tallahassee Democrat, 10/11/96, A12

Human Genome Research

New DNA-based Tests

Public Issues

regulation of commercial testing

genetic discrimination

# Considerations in Using New Genetic Tests

- Predictive Power
  - Clinical validity
- Psychosocial Potency
  - Intrafamilial tensions
  - Genetic discrimination risk
- Patients' Privileges
  - Pediatric testing
- Prophylactic Potential
  - Problem of pleiotropy

“As harsh as it sounds in an egalitarian society like ours, solidarity stops at a negative genetic test”

R. Porkorski, “Insurance Underwriting in the Genetic Era,” *American Journal of Human Genetics*, January, 1999

# Ego-genomics and “DNA Cream”

“A customer visits a Lab21 counter at Saks Fifth Avenue and completes the SkinProfiler questionaire. Then a beauty consultant takes a small sample of skin cells via a diagnostic tape applied to the arm. The tape takes off thousands of cells that will then be sent to the lab and read by the RT-PCR machine. Lab21’s scientists will be looking for four markers relevant to good skin. Based on that information, Lab21 will customize a DNA cream with appropriate levels of active ingredients to help boost any measured deficiencies. The treatment will sell for $250 and be shipped in less than a week.”

# Regulation of Genetic Testing

## Current

- New Test Introduction:
  - Professional consensus on clinical validity
- Test kits and products:
  - FDA evaluation for analytic validity and reliability
- Laboratory Testing Services:
  - CLIA evaluation for proficiency and quality.

- Walters, et. al, 1992: Genetic Screening Advisory Committee should evaluate all new tests
- NAS/IOM, 1993: ditto
- NIH Genetic Testing Task Force, 1996: HHS Advisory Committee on Genetic Testing should set standards
- SACGT, 2000: FDA should develop capacity to evaluate new tests for clinical and social validity

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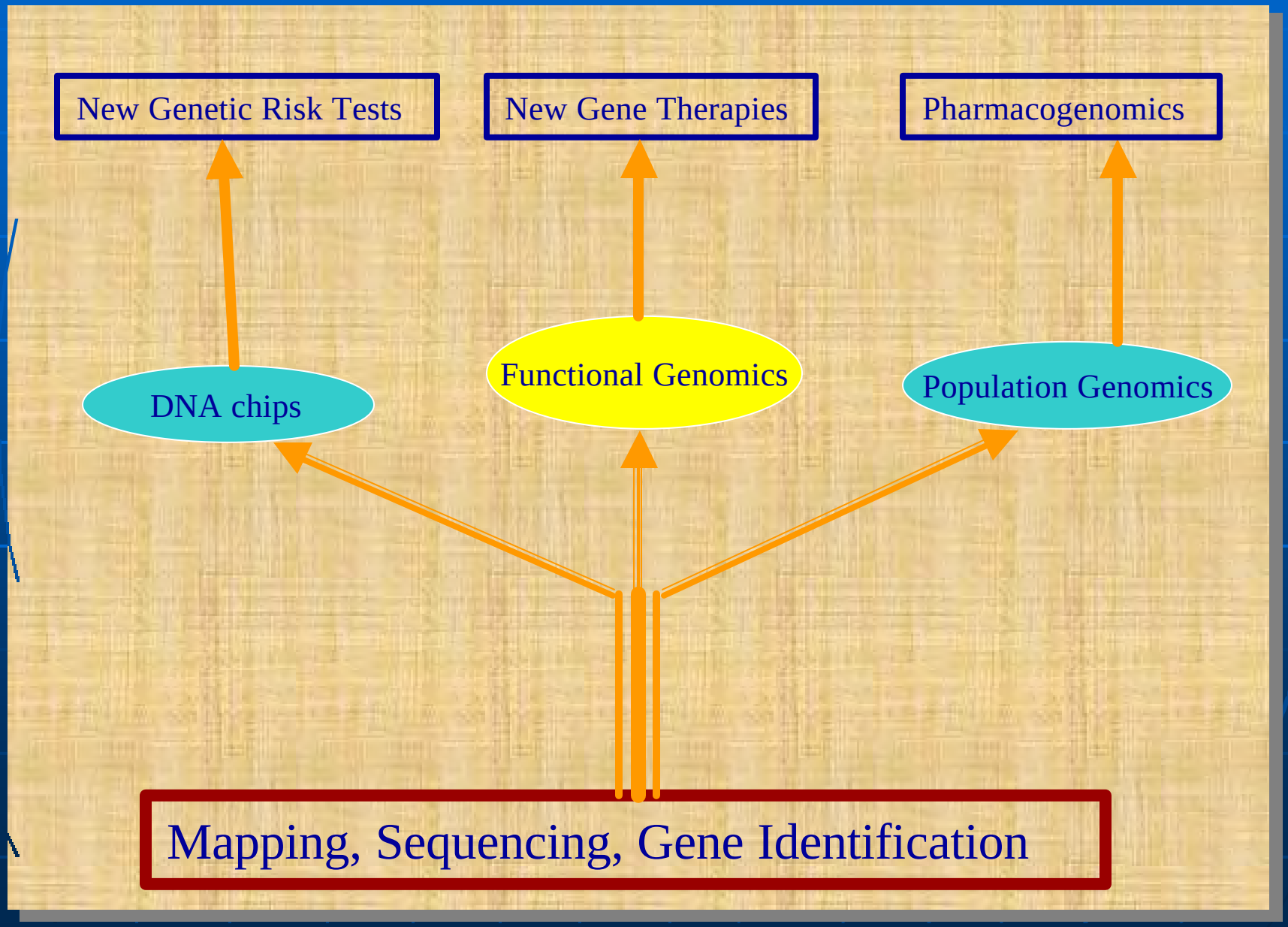
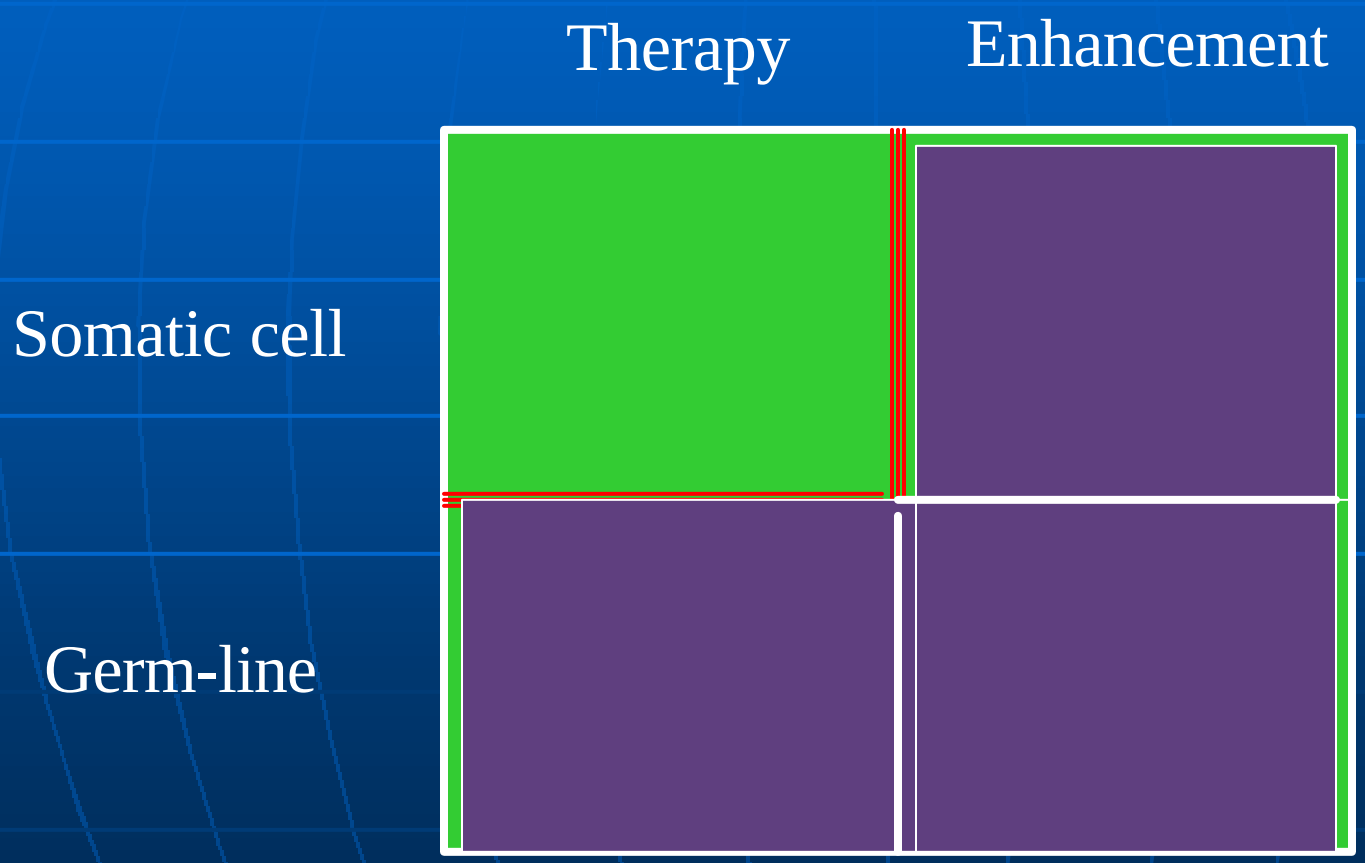
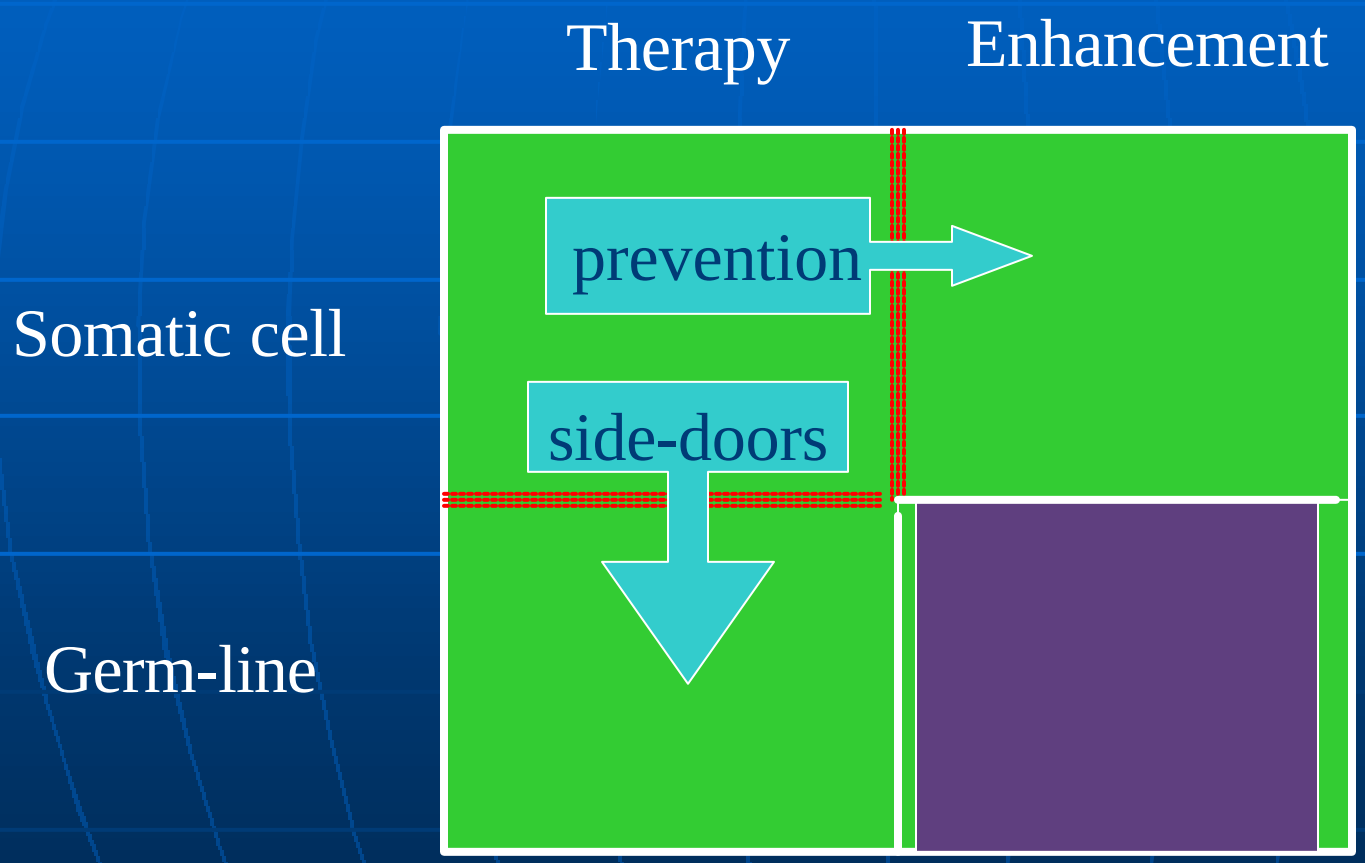


# Limits of Human Gene Transfer, c. 2000



# Limits of Human Gene Transfer, c. 2020?



# Scope of the NIH Guidelines

## Current definition of human gene transfer research:

"experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into human subjects."

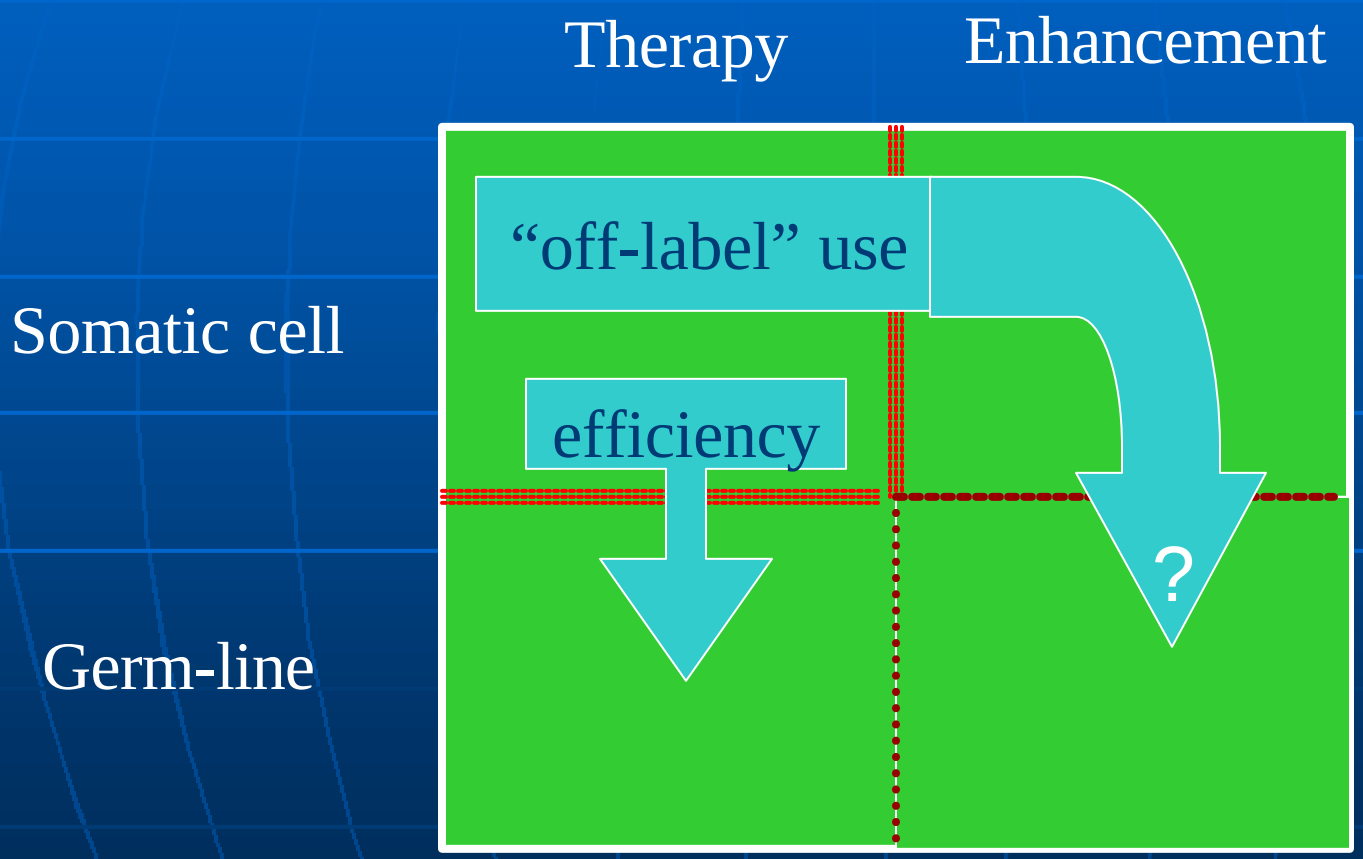
(NIH guidelines, Section I-A-1-a)

## Proposed new definition:

"For the purpose of the NIH Guidelines, gene transfer researc h in human subjects is defined as the administration of genetic material(s), including DNA, RNA, oligonucleotide molecules, chromosomes, mitochondria and nulei, in order to modify or manipulate the human genome, the expression of a gene(s), gene product(s) or to alter the biological properties of living cells. Examples of such processes include, but are not limited to, the administration of sequence specific oligonucleotides to alter a DNA sequence, administration of artificial or natural chromosomes, and transfer of genome containing organelles such as mitochondria or nuclei."

(Minutes of RAC meeting, 9-14-00)

# Limits of Human Gene Transfer, c. 2030?

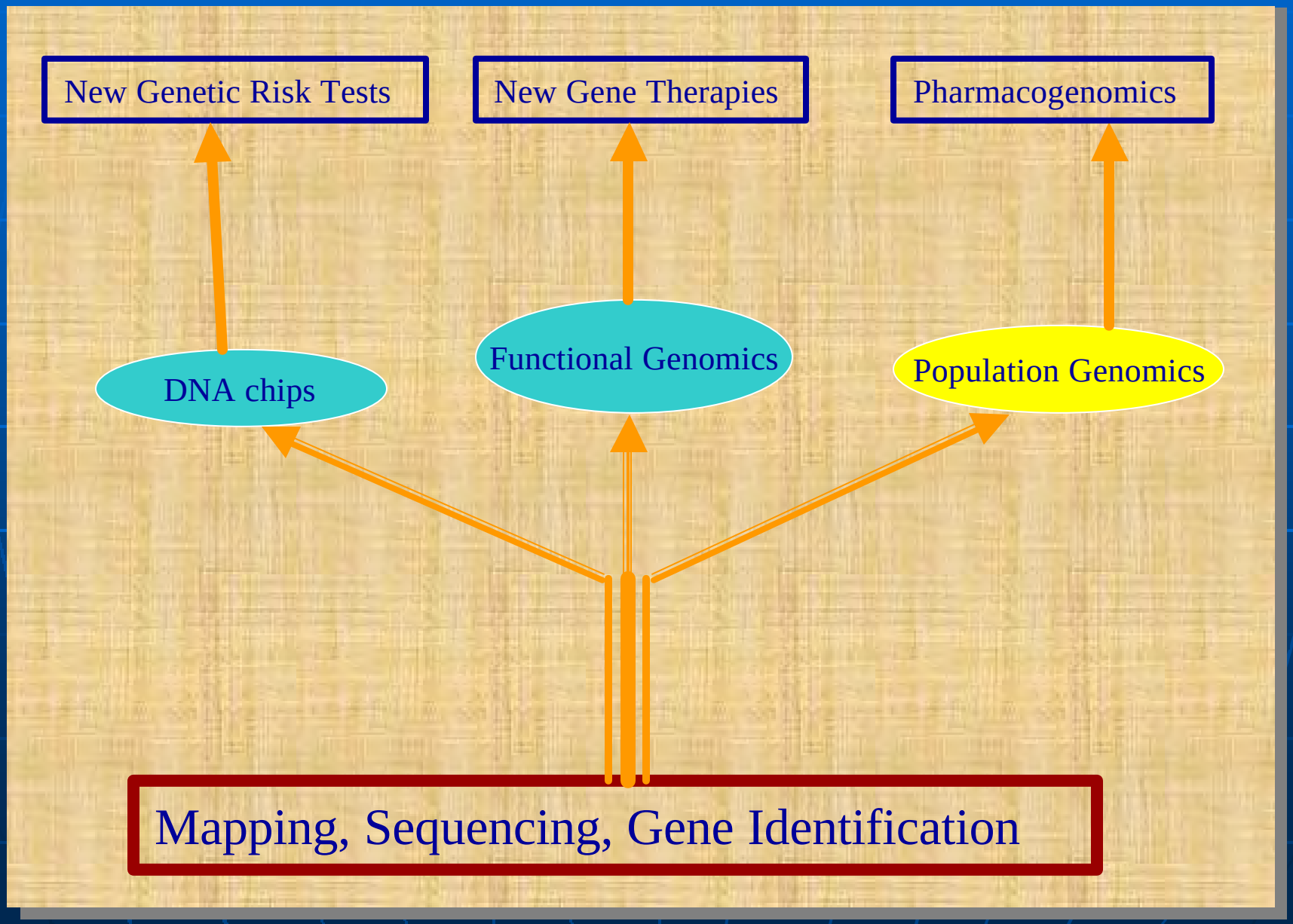


# Ego-genomics, part II

- "Now, through the World Anti-Doping Agency, the I.O.C. wants to anticipate the possibility that athletes will begin using gene therapy to strengthen their muscles, increase their oxygen-carrying capacity, block their pain or speed their pace of healing from injury"

  NYT March 21, 2002

# Post-Genome Project Genomics (after F. Collins)

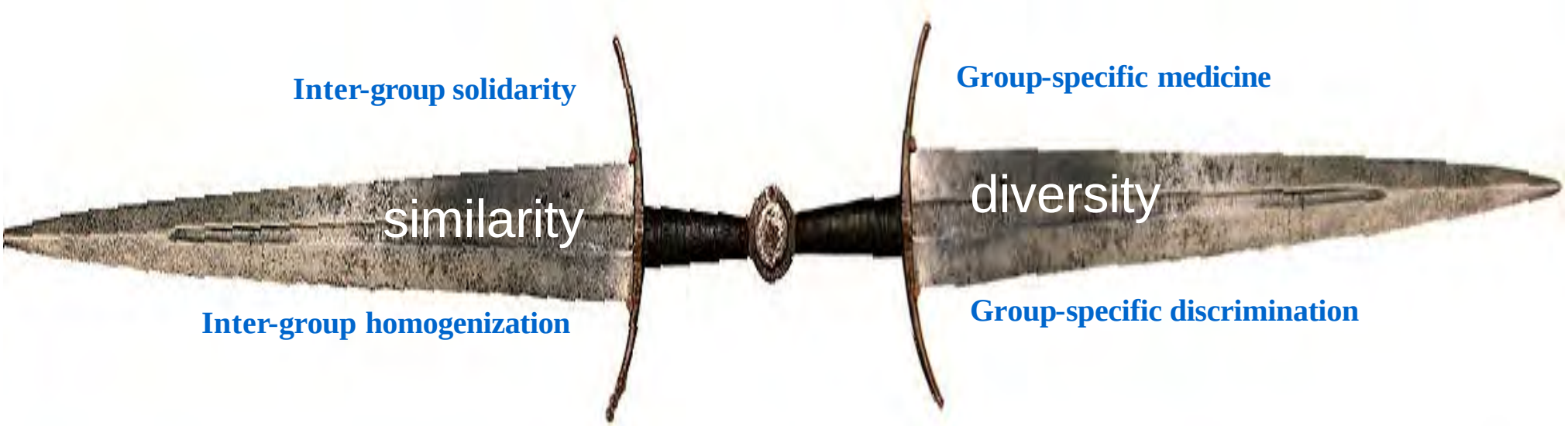


# Progeny of the Human Genome Project

- NSF: Human Genome Diversity Project, 1992-1998
- CDC: Public Health Genetics Program, 1997-
- NIEHS: Environmental Genome Project, 1998-
- NHGRI: The SNiP Consortium, 1998-2000
- NIGMS: Pharmacogenomics Initiative, 1999-
- NHGRI: The Haplotype Map, 2003-

All involve "comparative population genomics:"
I.e.,collecting DNA samples from members of different human groups for comparative analysis

# Comparative Population Genomics as a Practical Biomedical Tool



- Geneticist Kenneth Kidd of Yale University says the DNA samples he's examined show that there is "a virtual continuum of genetic variation" around the world. "There's no place where you can draw a line and say there's a major difference on one side of the line from what's on the other side." If one is talking about a distinct, discrete, identifiable population, Kidd adds, "there's no such thing as race in [modern] *Homo sapiens*."

# Ego-Genomics, Part III

"A company in Sarasota, FL, is offering a DNA test that it says will measure customer's racial ancestry and their ancestral proportions."

Claiming to be 'the world's first recreational genomics testing service,' DNAPrint Genomics, Inc., says its test will be useful for people interested in their own origins as well as for more practical purposes, like "to validate your eligibility for race-based college admissions or government entitlements."

NYT, 10/1/2002

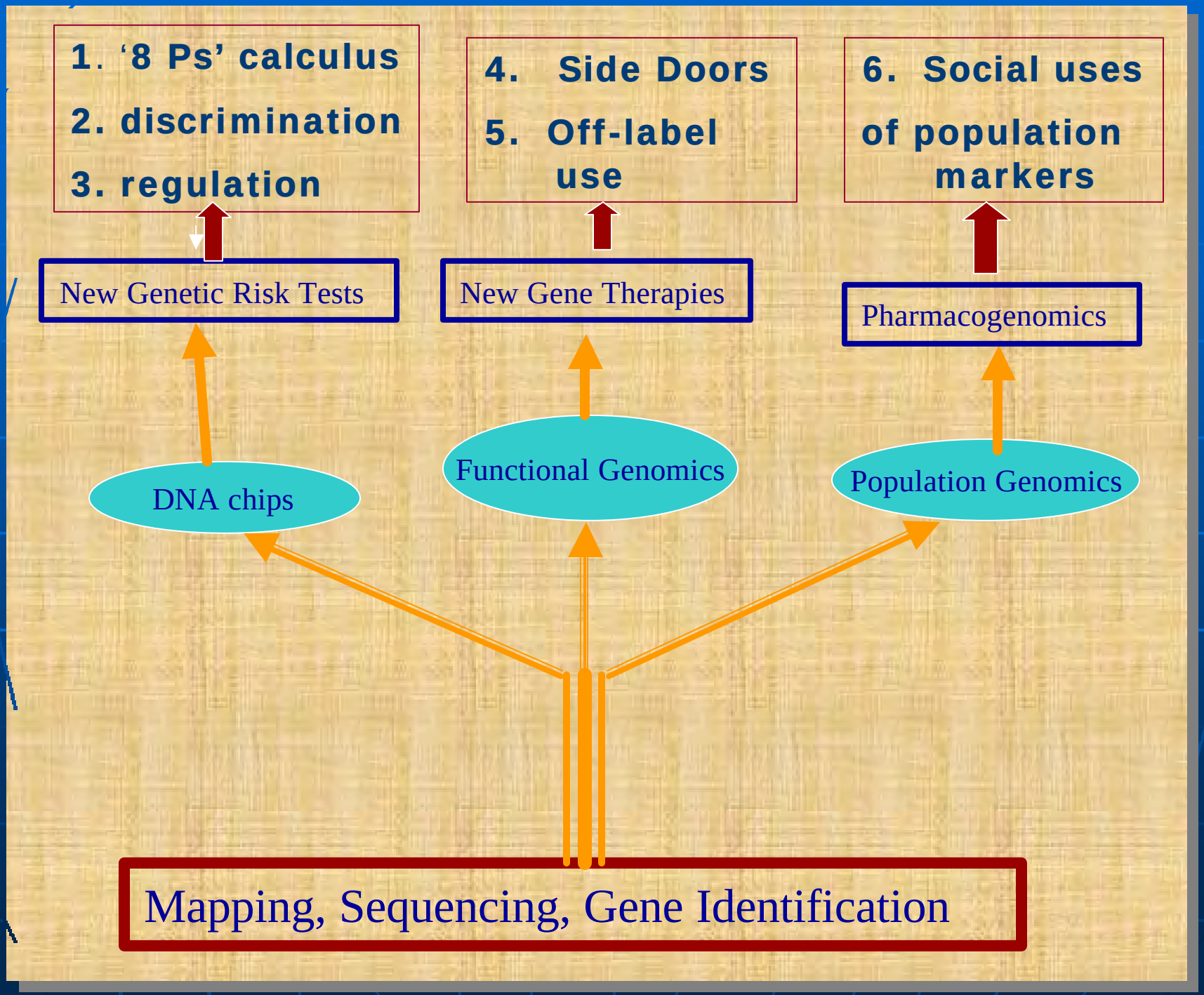
“Have you ever wondered whether you are of purely Indo-European origin or a blend of Indo-European and Native American (or other) ancestry? We have developed **ANCESTRYbyDNA** to provide you this information from your own DNA.

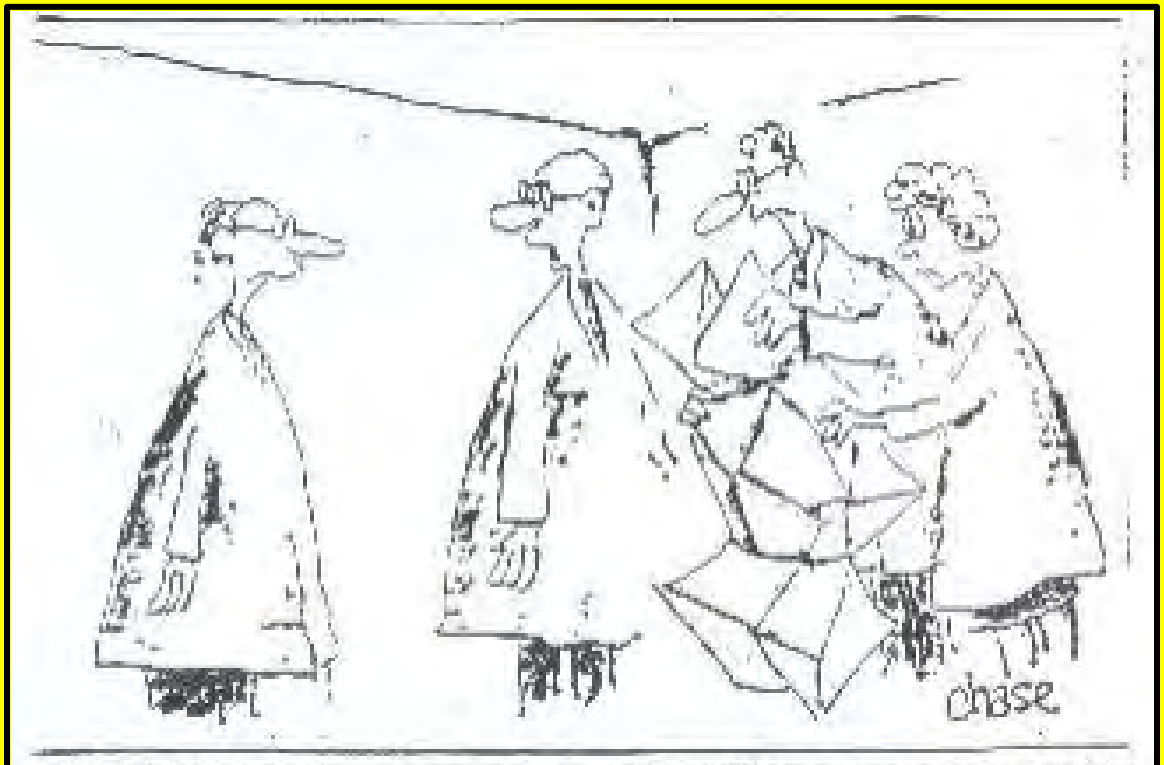
**ANCESTRYbyDNA** is a new type of genetic test called *Bio Geographical Ancestry test*, capable of determining your precise ancestral proportions. For example, it might reveal that you are of 80% African and 20% Indo-European, or 95% African and 5% Indo-European ancestry (or some other mix/ratio, as the case may be).”

- **“Who is interested in the test?**

- We have sold the test to Genealogists with a desire to learn about ambiguous regions of their family trees.
- The test is attractive for the adopted, for people that are simply curious and even for medical patients. One customer used the test to hone their search for an organ donor.

- Another suspected he was of significant Native American heritage, but had no way to prove it. **The results of the test gave him a sound basis by which to claim access to commercial opportunities reserved for individuals of Native American descent.**
- Whether your goal is to validate your eligibility for race-based college admissions or government entitlements, or whether you are just curious, the patent-pending **ANCESTRYbyDNA** test is the only scientifically rigorous method available for this purpose in existence today.”


1. '8 Ps' calculus
2. discrimination
3. regulation
4. Side Doors
5. Off-label use
6. Social uses of population markers
New Genetic Risk Tests
New Gene Therapies
Pharmacogenomics
DNA chips
Functional Genomics
Population Genomics
Mapping, Sequencing, Gene Identification




"We finished the genome map, now we can't figure out how to fold it!"